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| 09/985,873  | 11/06/2001  | Tione Buranda        | UNME-0100-1         | 4518             |
| 28156   | 7590        | 02/28/2005           | EXAMINER            |                  |
| COLEMAN SUDOL SAPONE, P.C.<br>714 COLORADO AVENUE<br>BRIDGE PORT, CT 06605-1601 |             |                      | LAM, ANN Y          |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1641                |                  |
| DATE MAILED: 02/28/2005   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/985,873

Applicant(s)

BURANDA ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 28-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/6/01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of group I in the reply filed on October 4, 2004 is acknowledged. The traversal is on the ground(s) that the groups are interrelated, and thus can be examined together with a significant degree of administrative efficiency and without placing a serious burden on Examiner. This is not found persuasive because examining the different groups would place a serious burden on Examiner given the different searches and considerations required in examining the different groups.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the ranges recited in claims 2-4, 6, 21, 23, 24 and 27 lack an antecedent basis in the specification.

### ***Claim Objections***

Claim 26 is objected to because of the following informalities: in line 2 of claim 26, "bead" should be --beads--. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "neighboring obstructive features" in line 1. There is insufficient antecedent basis for this limitation in the claim. (Applicant can overcome the rejection by, for example, deleting "neighboring" and "of said obstructive features". Alternatively, Applicant can include an antecedent basis for "neighboring obstructive features".)

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 2, 4-10, 12-15, 17, 22 and 25 are rejected under 35

U.S.C. 102(e) as being anticipated by Wilding et al., 5,637,469.

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Wilding teaches a sensing device comprising:

a vessel (22);

a plurality of sensor beads (col. 14, lines 38-41) located within said vessel to form interstitial spaces therethrough; and

a plurality of biomolecules (e.g., polynucleotides, col. 14, line 40) bound to at least a portion of said plurality of beads, each of said biomolecules having a fluorescent tag (i.e., fluorescent label, col. 14, line 40, col. 4, line 3, col. 10, lines 17-26, col. 11, line 64, col. 12, lines 10, 25, 36 and 40, col. 13, line 13, and col. 15, line 5.)

As to claim 2, the vessel as a width of 250 um to 500 um (col. 2, lines 51-53.)

As to claim 4, the vessel has a depth of 50 um to 100 um (col. 2, line 55.)

As to claim 5, the plurality of beads (col. 12, line 10) are located in microfluidic channels in the vessel.

As to claim 6, the microfluidic channels have a width of 10 um to 500 um (col. 2, line 53.)

As to claim 7, the microfluidic channels are comprised of optically transparent material (col. 10, line 3; and col. 12, line 1; col. 7, lines 39, and lines 42-45.)

As to claim 8, the optically transparent material comprise glass (col. 7, line 39 .

As to claim 9, the optically transparent material comprise quartz (col. 7, line 39.)  
(Glass is made of quartz.)

As to claim 10, the optically transparent material comprises a polymer (i.e, plastic, col. 7, line 59.)

As to claim 12, the plurality of sensor beads comprises at least two different types of sensor beads (i.e., beads with different biomolecules attached, col. 12, line 11.)

As to claim 13, the plurality of biomolecules comprises at least two different kinds of biomolecules (col. 12, line 11).

As to claim 14, each of the two different kinds of biomolecules includes a different fluorescent tag (col. 12, line 11, and col. 11, line 64.)

As to claim 15, the sensing device comprises at least two sensing regions, each of said sensing regions including one of said at least two different kinds of biomolecules (col. 12, lines 10-13.)

As to claim 17, said plurality of beads comprise at least two different kinds of beads and each of said different kinds of biomolecules are bound to a respective type of said at least two different types of sensor beads (col. 12, lines 10-13.) (The beads are considered different kinds of beads in that that they are capable of binding to different antibodies.)

As to claim 22, the vessel includes obstructive features (i.e., features creating a magnetic field, col. 9, lines 54-65) therein for preventing said sensor beads from flowing along said vessel .

As to claim 25, said sensor beads are coated with at least one coating of said plurality of biomolecules (col. 11, lines 54-57.)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 3 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al., 5,637,469.

As to claim 3, Wilding does not disclose that the vessel has a specific length of 0.5 cm to 3.0 cm.

However, Wilding teaches that the length of a channel may be designed to permit the timed mixing and addition of sample and reagent components (col. 15, lines 20-22.) Wilding also teaches various embodiments having chambers of .5 cm (i.e., 5.2 mm lengths, col. 20, line 7, and col. 21, line 47.)

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Forming the length of the vessel containing beads to 0.5 cm to 3.0 cm provides a workable or optimum range for containing or mixing particular sample and reagent components, and thus discovering this workable or optimum range involves only routine skill in the art.

As to claim 27, Wilding does not disclose that the interstitial spaces each has a volume of 1 nL to 1000 nL.

However, Wilding teaches that the volume of the detection chamber can be decreased to increase rate of reaction (col. 8, lines 16-20), and that the device may be

microfabricated with microliter volumes, or nanoliter volumes or less, which advantageously limits the amount of sample and/or reagent fluids required for an assay (col.8, lines 23-27.)

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Forming the Wilding device such that the interstitial spaces each has a volume of 1 nL to 1000 nL provides a workable or optimum range for a desired rate of reaction or amount of sample and reagent fluids required for an assay, and thus discovering this workable or optimum range involves only routine skill in the art.

3. Claims 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al., 5,637,469, in view of Kapur et al., 6,548,263.

Wilding discloses the invention substantially as claimed (see above with respect to claims 1 and 10.) More specifically, Wilding discloses that the device comprises a transparent cover to permit optical detection of analyte binding (col. 10, lines 3-4, and lines 9-10.) Wilding further discloses that the cover may be glass or plastic (col. 7, line 59.) However, Wilding does not specifically disclose that the plastic comprises poly(dimethylsiloxane).

Kapur, similar to Wilding, discloses a detection device comprising chambers and channels (col. 19, lines 30-33, and lines 46-47; col. 20, lines 53-61; and col. 21, lines

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38-50.) Kapur further discloses that the device may be formed from poly(dimethylsiloxane), (col. 20, lines 55-61.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use poly(dimethylsiloxane) as the transparent plastic to form the Wilding device, including cover, as taught by Kapur, since such plastic is well known and conventional in the art in forming an assay device comprising chambers and channels that permit optical detection of analyte binding.

4. Claims 16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al., 5,637,469, in view of Mian et al., 6,319,469.

Wilding discloses the invention substantially as claimed (see above). More specifically, Wilding discloses that a plurality of binding regions housing different antibodies (and beads) may be fabricated in the flow paths to allow for simultaneous assays in one device (col. 12, lines 10-13.)

However, Wilding does not disclose the mechanism by which the different antibodies are housed in the different binding regions. More specifically, as to claim 16, Wilding does not disclose that the vessel includes obstructive features therein for preventing flow of said sensor beads between said at least two sensing regions. As to claim 23, Wilding does not disclose that neighboring obstructive features of said obstructive features are located 5 um to 20 um from each other.

Mian, similar to Wilding, discloses a flow cytometry device (col. 23, line 25) including beads for the detection of molecules (col. 42, lines 46-48.) Mian further

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discloses that the beads are retained in a channel by a filter (col. 42, lines 48-49.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a filter as taught by Mian in the Wilding flow cytometry device, as a well known and conventional means to retain analyte binding beads in a channel in a flow cytometry device.

5. Claims 18-21, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al., 5,637,469, in view of Kraus et al., 5,925,567.

Wilding discloses the invention substantially as claimed (see above with respect to claim 1). More specifically, Wilding teaches that the device is useful for a wide range of applications including detection of cells or macromolecules (see last sentence of abstract.)

However, Wilding does not disclose spacer beads (claim 18), nor foundation beads (claim 19) within the vessel, nor beads having the specific diameter claimed (claims 21 and 24), nor biotin as the means to bind biomolecules to beads (claim 26).

Kraus, like Wilding, teaches a device comprising a chamber containing beads having affinity to specific molecules for selective binding (col. 2, lines 32-34, and col. 5, lines 41-42.) As to claims 18 and 19, Kraus also teaches spacer beads comprising non-activated beads at the top, bottom or a specific region of a column or mixed with activated beads in order to reduce cell-to-cell interactions (col. 10, lines 42-45.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide spacer beads at the top, bottom or specific region of the

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Wilding column or mixed with activated beads in the Wilding column in order to reduce cell-to-cell interactions as taught by Kraus as would be desirable for more accurate results. (The spacer beads at the bottom of the column are considered foundation beads.)

As to claim 20, Kraus also teaches that the beads can be made of glass (col. 5, line 41.)

It would have been obvious to one of ordinary skill in the art to use glass as the material to form the beads as taught by Kraus as a well known and conventional material used for forming beads as a solid support for binding to materials.

As to claims 21 and 24, Kraus teaches that the beads have a diameter of 250 to 550 um, and that such diameters allow flow of cells through the column and yet provide sufficient surface area to enable efficient cell interaction (col. 10, line 38.) (It appears that Kraus is referring to both spacer and sensor beads, see column 10, lines 33-45.)

It would have been obvious to one of ordinary skill in the art to form the Wilding sensor and foundation beads such that it has a diameter of 250 to 550 um in order to allow for flow of cells through the column and yet provide sufficient surface area to enable efficient cell interaction as taught by Kraus, as would be desirable for more accurate results and easier usage.

As to claim 26, Kraus teaches biotin as the means to bind molecules to beads (col. 8, lines 64-66.) It would have been obvious to one of ordinary skill in the art to use biotin as the means to bind molecules to beads in the Wilding device as taught by Kraus, as a well known and conventional means to bind molecules to beads.


**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

  
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2/22/05